

MIELODEC



Fixative and decalcifier for bone marrow biopsy

IVD In-vitro diagnostic medical device
BASIC UDI: 080339762W01030705X2
IVD in **Classe A**, Reg. UE 2017/746

Catalog number	UDI-DI
04-230827	08033976231521

Volumetric ratio	specimen volume/ fixative volume 1:50 specimen volume /decalcifying solution volume 1:50
Procedure time	3 hours and 15 minutes
Product validity	2 years
Storage temperature	15-25 °C
Complementary equipment	not requested

Expected aim Product for the preparation of cyto-histological samples for optical microscopy.

Application Decalcifying fixative for bone marrow biopsy in the study of hematologic diseases.

Principle The kit includes 2 reagents: fixative and decalcifier.

- B5 fixative is recommended for hematopoietic tissues; it contains formalin and mercury in a buffer solution. Concentration of mercury chloride has been chosen so that no mercury will precipitate on section during decalcifying process, provided that suggested procedure times are followed.
- Decalcifier contains E.D.T.A. (ethylenediaminetetracetic acid) in acid buffer. Decalcifying process takes place through chelation in acid environment and preserves tissue morphology in a remarkably short time for histopathological routine.

Method

- 1) Put bone marrow immediately after drawing in reagent A (fixative): leave to act 90 minutes.
- 2) Extract the fragment from solution A and put it in 70° ethanol for 15 minutes (the fragment can be left for an indefinite time)
- 3) Put the biopsy in reagent B (decalcifier) : leave to act 90 minutes.
- 4) Dehydrate through ascending alcohols, clear in xylene and embed in paraffin.

ATTENTION:

Suggested procedure times have been tested on cylinders of bone marrow biopsy 3 mm thick, taken from crista iliaca and sternum. Decalcification times should be prolonged for compact bone and larger fragments. We recommend to avoid fragments thicker than 5 mm.

Reagents	A) B5 modified, 5 x 100 ml B) E.D.T.A. in acid buffer, 5 x 100 ml
Warning and precaution	The product is intended for professional laboratory use for healthcare professionals. Carefully read the information on the label (danger symbols, risk and safety phrases) and always consult the safety data sheet. Do not use if the primary container is damaged. In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.
Storage	Store the preparation at room temperature. Keep the containers tightly closed.
Stability	After the first opening, the product is reusable until the expiry date, if correctly stored.
Disposal	Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.
References	

REVISION N°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022